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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,389	01/03/2002	Y. Tom Tang	PF-0715 USN	9245

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FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
SZPERKA, MICHAEL EDWARD	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,389	TANG ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-81* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claims 1, 2, 16, 17, and 39, drawn to an isolated **polypeptide** and a composition containing a polypeptide that corresponds to SEQ ID NO: 1.

Group 2, claims 1, 2, 16, 17, and 40,drawn to an isolated **polypeptide** and a composition containing a polypeptide that corresponds to SEQ ID NO: 2.

Group 3, claims 1, 2, 16, 17, and 41, drawn to an isolated **polypeptide** and a composition containing a polypeptide that corresponds to SEQ ID NO: 3.

Group 4, claims 1, 2, 16, 17, and 42, drawn to an isolated **polypeptide** and a composition containing a polypeptide that corresponds to SEQ ID NO: 5.

Group 5, claims 1, 2, 16, 17, and 43, drawn to an isolated **polypeptide** and a composition containing a polypeptide that corresponds to SEQ ID NO: 6.

Group 6, claims 1, 2, 16, 17, and 44, drawn to an isolated **polypeptide** and a composition containing a polypeptide that corresponds to SEQ ID NO: 7.

Group 7, claims 1, 2, 16, 17, and 45, drawn to an isolated **polypeptide** and a composition containing a polypeptide that corresponds to SEQ ID NO: 8.

Group 8, claims 1, 2, 16, 17, and 46, drawn to an isolated **polypeptide** and a composition containing a polypeptide that corresponds to SEQ ID NO: 9.

Group 9, claims 1, 2, 16, 17, and 47, drawn to an isolated **polypeptide** and a composition containing a polypeptide that corresponds to SEQ ID NO: 10.

Group 10, claims 3-7, 9, 11, 12, 30, and 48, drawn to an isolated **polynucleotide** encoding SEQ ID NO: 11, a host cell to encode same, and a method for producing polypeptides from said host cell.

Group 11, claims 3-7, 9, 11, 12, 31, and 49, drawn to an isolated **polynucleotide** encoding SEQ ID NO: 12, a host cell to encode same, and a method for producing polypeptides from said host cell.

Group 12, claims 3-7, 9, 11, 12, 32, and 50, drawn to an isolated **polynucleotide** encoding SEQ ID NO: 13, a host cell to encode same, and a method for producing polypeptides from said host cell.

Group 13, claims 3-7, 9, 11, 12, 33, and 51, drawn to an isolated **polynucleotide** encoding SEQ ID NO: 15, a host cell to encode same, and a method for producing polypeptides from said host cell.

Group 14, claims 3-7, 9, 11, 12, 34, and 52, drawn to an isolated **polynucleotide** encoding SEQ ID NO: 16, a host cell to encode same, and a method for producing polypeptides from said host cell.

Group 15, claims 3-7, 9, 11, 12, 35, and 53, drawn to an isolated **polynucleotide** encoding SEQ ID NO: 17, a host cell to encode same, and a method for producing polypeptides from said host cell.

Group 16, claims 3-7, 9, 11, 12, 36, and 54, drawn to an isolated **polynucleotide** encoding SEQ ID NO: 18, a host cell to encode same, and a method for producing polypeptides from said host cell.

Group 17, claims 3-7, 9, 11, 12, 37, and 55, drawn to an isolated **polynucleotide** encoding SEQ ID NO: 19, a host cell to encode same, and a method for producing polypeptides from said host cell.

Group 18, claims 3-7, 9, 11, 12, 38, and 56, drawn to an isolated **polynucleotide** encoding SEQ ID NO: 20, a host cell to encode same, and a method for producing polypeptides from said host cell.

Groups 19-27, claim 8, drawn to **a transgenic organism** containing SEQ ID NO: 11 through SEQ ID NO: 13 and SEQ ID NO: 15 through SEQ ID NO: 20, respectively.

Groups 28-36, claims 10, 58, 59, and 61, drawn to **an antibody** that binds SEQ ID NO: 1 through SEQ ID NO: 3 and SEQ ID NO: 5 through SEQ ID NO: 10, respectively.

Groups 37-45, claims 13-15, drawn to **a method for detecting a polynucleotide** of SEQ ID NO: 11 through SEQ ID NO: 13 and SEQ ID NO: 15 through SEQ ID NO: 20, respectively.

Groups 46-54, claim 18, drawn to **a method of treating a disease associated with decreased expression of an IMUN by administering a composition containing a polypeptide** that correspond to SEQ ID NO: 1 through SEQ ID NO: 3 and SEQ ID NO: 5 through SEQ ID NO: 10, respectively.

Groups 55-63, claim 19, drawn to **a method of screening for an agonist compound** that uses polypeptides corresponding to SEQ ID NO: 1 through SEQ ID NO: 3 and SEQ ID NO: 5 through SEQ ID NO: 10, respectively.

Groups 64-72, claim 20, drawn to **an agonist composition** that was identified in an assay that used a polypeptide corresponding to SEQ ID NO: 1 through SEQ ID NO: 3 and SEQ ID NO: 5 through SEQ ID NO: 10, respectively, wherein said composition **does not contain the peptide** used in identifying the agonist.

Groups 73-81, claim 21, drawn to **a method of treating a disease by administering an agonist composition** that was identified in an assay that used a polypeptide corresponding to SEQ ID NO: 1 through SEQ ID NO: 3 and SEQ ID NO: 5 through SEQ ID NO: 10, respectively, wherein said composition **does not contain the peptide** used in identifying the agonist.

Groups 82-90, claim 22, drawn to a **method of screening for an antagonist compound** that uses polypeptides corresponding to SEQ ID NO: 1 through SEQ ID NO: 3 and SEQ ID NO: 5 through SEQ ID NO: 10, respectively.

Groups 91-99, claim 23, drawn to **an antagonist composition** that was identified in an assay that used a polypeptide corresponding to SEQ ID NO: 1 through SEQ ID NO: 3 and SEQ ID NO: 5 through SEQ ID NO: 10, respectively, wherein said composition **does not contain the peptide** used in identifying the antagonist.

Groups 100-108, claim 24, drawn to **a method of treating a disease by administering an antagonist composition** that was identified in an assay that used a polypeptide corresponding to SEQ ID NO: 1 through SEQ ID NO: 3 and SEQ ID NO: 5 through SEQ ID NO: 10, respectively, wherein said composition **does not contain the peptide** used in identifying the antagonist.

Groups 109-117, claim 25, drawn to **a method of screening for compounds that bind** SEQ ID NO: 1 through SEQ ID NO: 3 and SEQ ID NO: 5 through SEQ ID NO: 10, respectively.

Groups 118-126, claim 26, drawn to a method of **screening for compounds that modulate the activity** of the polypeptides of SEQ ID NO: 1 through SEQ ID NO: 3 and SEQ ID NO: 5 through SEQ ID NO: 10, respectively.

Groups 127-135, claims 27 and 29, drawn to **a method of screening for compounds that alter the expression** of polynucleotides corresponding to SEQ ID NO: 11 through SEQ ID NO: 13, and SEQ ID NO: 15 through SEQ ID NO: 20, respectively.

Groups 136-144, claim 28, drawn to **a method of assessing toxicity** utilizing polynucleotides that correspond to SEQ ID NO: 11 through SEQ ID NO: 13, and SEQ ID NO: 15 through SEQ ID NO: 20, respectively.

Groups 145-153, claim 57, drawn to **a diagnostic test using an antibody** that binds SEQ ID NO: 1 through SEQ ID NO: 3 and SEQ ID NO: 5 through SEQ ID NO: 10, respectively.

Groups 154-162, claims 60 and 62, drawn to **a method of diagnosing a condition or disease** using an antibody that binds SEQ ID NO: 1 through SEQ ID NO: 3 and SEQ ID NO: 5 through SEQ ID NO: 10, respectively.

Groups 163-171, claims 63-70, drawn to **a method of making an antibody** that binds SEQ ID NO: 1 through SEQ ID NO: 3 and SEQ ID NO: 5 through SEQ ID NO: 10, respectively.

Groups 172-180, claim 71, drawn to **a method of detecting a polypeptide** that contains SEQ ID NO: 1 through SEQ ID NO: 3 and SEQ ID NO: 5 through SEQ ID NO: 10, respectively.

Groups 181-189, claim 72, drawn to **a method of purifying a polypeptide** than contains SEQ ID NO: 1 through SEQ ID NO: 3 and SEQ ID NO: 5 through SEQ ID NO: 10, respectively.

Group 190, claims 73 and 75-81, drawn to **a microarray**.

Group 191, claim 74, drawn to **a method of generating a transcript image**.

2. The inventions listed as Groups 1-191 do not relate to a single general inventive concept under PTC Rule 13.1 because, under PTC Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

As was found in the International Search Report, the Inventions of Group 1, a polypeptide comprising SEQ ID NO: 1, and Group 10, a polynucleotide comprising SEQ ID NO: 11, were found to have no special technical feature that defined a contribution over the prior art of Nagase et al. ("Prediction of the coding sequences of unidentified human genes. 17. The complete sequences of 100 new cDNA clones from brain which code for large proteins in vitro." 2000, DNA Res. 7:143-150), and the SWALL and EMBL databases.

Since Applicant's Inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

For examination purposes it has been noted that the terms agonist and antagonist are used in the absence of readily apparent structural features, and as such it is unclear as to what Applicant has claimed. The terms agonist and antagonist have been interpreted to mean a compound that does not contain a peptide selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 3 and SEQ ID NO: 5 through SEQ ID NO: 10, and has activity as an agonist or antagonist in a biological assay system. The specification does not appear to indicate an assay for testing biological function, nor does it appear to clearly state the biological activity that would be required

of an agonist or antagonist. Applicant is invited to clarify what the terms agonist and antagonist mean, and more fully define their biological function.

Further, it is noted that the claims are drawn to patentably distinct products that differ in structure, and methods for making and using said distinct products. These distinct products and methods have been set forth in the groups above. If Applicant claims other products, combinations of products, methods, or combination of methods, the claims may be subject to further restriction. Therefore, the restriction is set forth for each of the various groups, irrespective of the format of the claims.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

In groups 46-54, 73-81, 100-108, and 145-162, the ultimate species of disease that is being treated or diagnosed should be elected from the list contained on page 34, line 27 to page 35, line 12. These species are distinct because they differ their symptoms, etiology and therapeutic endpoints. Thus the diseases require different method steps and different products for their treatment and diagnosis.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claims 1, 18, 21, 24, 57, 60, and 62 are generic for example.

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The diseases found in the list contained on page 34, line 27 to page 35, line 12 are all well known in the art, and as such they do not have a special technical feature associated with them.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Szperka, Ph.D.
Patent Examiner
Technology Center 1600
September 21, 2004

Patrick J. Nolan, Ph.D.
Primary Examiner